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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------|-------------|----------------------|---------------------|-------------------|
| 09/673,139 | 06/12/2001 | Peter Allen Revell | 23530-0003 | 9561 |
| 909 | 7590 | 11/04/2004 | | |
| PILLSBURY WINTHROP, LLP | | | | EXAMINER |
| P.O. BOX 10500 | | | | ROBERT, EDUARDO C |
| MCLEAN, VA 22102 | | | | ART UNIT |
| | | | | PAPER NUMBER |
| | | | | 3732 |

DATE MAILED: 11/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

| | | | |
|-----------------|-------------------|--------------|---------------|
| Application No. | 09/673,139 | Applicant(s) | REVELL ET AL. |
| Examiner | Eduardo C. Robert | Art Unit | 3732 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 27 July 2004.
2a) This action is **FINAL**. 2b) This action is non-final.
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1,2,4-16,18-24 and 26 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) Claim(s) _____ is/are allowed.
6) Claim(s) 1,2,4-13,15,16,18-24 and 26 is/are rejected.
7) Claim(s) 14 is/are objected to.
8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
10) The drawing(s) filed on 11 October 2000 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) Notice of Informal Patent Application (PTO-152)
6) Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4-13, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Constantz (U.S. Patent 5,188,670).

Constantz discloses an implant of metal or alloy, e.g. titanium alloy (see col. 7, lines 1-5) having a hydroxyapatite coating that the coating can have incorporated therein a variety of ions, as required (see col. 2, lines 64-68). It is noted that the ions comprise fluorine ions. Furthermore, the implant of Constantz appears to be substantially identical to the implant claimed, although produced by a different process (different than ion beam implantation), therefore the burden is upon the applicant to come forward with **evidence** establishing an unobvious difference between the two. In re Marosi, 218 USPQ 289 (Fed. Cir. 1983). Constantz discloses the claimed invention except for the ions being incorporated into the surface of the implant up to a maximum depth of 200 nm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct implant disclosed by Constantz with the ions being incorporated into the surface of the implant up to a maximum depth of 200 nm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. It is noted that this maximum depth of 200 nm would be a level whereby ongrowth onto the implant is

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enhanced. Moreover, with regard to claims 4-6, i.e. up to a maximum depth of 150 nm (claim 4), or up to a maximum depth ranging up to approximately 100 nm (claim 5), or the ions being presented at a level between 1×10^{10} and 1×10^{18} ions per cm^2 of the surface (claim 6), it would have been further obvious to one having ordinary skill in the art at the time the invention was made to construct implant disclosed by Constantz with the ions being incorporated into the surface of the implant up to a maximum depth of 150 nm, or up to a maximum depth ranging up to approximately 100 nm, or the ions being presented at a level between 1×10^{10} and 1×10^{18} ions per cm^2 of the surface, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. With regard to claim 10, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the implant of Constantz with the ions being magnesium or manganese, or zinc, or silicon, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claims 1, 2, 4-13, 15, 16, 18-24, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Natasi et al. (U.S. Patent 5,817,326).

Natasi et al. disclose an implant having a hydroxyapatite coating that the coating can have incorporated therein a ion (see abstract). Natasi, et al. disclose that any ions might be utilized in the ion implantation process (see col. 5, lines 25-27), thus this statement include ions of groups IIA, IVA, VIIA and transition elements. Natasi et al. disclose that the ions are incorporated via ion beam implantation. Natasi et al. disclose the claimed invention except for

the ions being incorporated into the surface of the implant up to a maximum depth of 200 nm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct implant disclosed by Natasi et al. with the ions being incorporated into the surface of the implant up to a maximum depth of 200 nm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. It is noted that this maximum depth of 200 nm would be a level whereby ongrowth onto the implant is enhanced. Moreover, with regard to claims 4-6 and 18-20, i.e. up to a maximum depth of 150 nm (claims 4 and 18), or up to a maximum depth ranging up to approximately 100 nm (claims 5 and 19), or the ions being presented at a level between 1×10^{10} and 1×10^{18} ions per cm^2 of the surface (claims 6 and 20), it would have been further obvious to one having ordinary skill in the art at the time the invention was made to construct implant disclosed by Natasi et al. with the ions being incorporated into the surface of the implant up to a maximum depth of 150 nm, or up to a maximum depth ranging up to approximately 100 nm, or the ions being presented at a level between 1×10^{10} and 1×10^{18} ions per cm^2 of the surface, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. With regard to claim 10, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the implant of Natasi et al. with the ions being magnesium or manganese, or zinc, or silicon, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Response to Arguments

Applicant's arguments filed on July 27, 2004 have been fully considered but they are not persuasive.

In response to applicant's argument about Constantz and the ion implantation method recitation in claim 1, "the ions are incorporated into or onto the surface of the bone implant by ion beam implantation", it is noted that the method of forming the device is not germane to the issue of patentability of the device itself. Therefore, this limitation has not given patentable weight. Furthermore, the device of appear to be substantially identical to the device claimed, although produced by a different process, therefore the burden is upon the applicant to come forward with **evidence** establishing an unobvious difference between the two. *In re Marosi*, 218 USPQ 289 (Fed. Cir. 1983).

In response to applicant's argument that the purposes of Constantz reference is not to alter the bioactivity of the surface of the coating, it is noted that the Constantz reference is used to reject an apparatus claim and not a method claim. Constantz, as modified, satisfies all the structural limitations set forth in the apparatus claim. Moreover, the fact that Applicant uses the ions for a different purpose does not alter the conclusion that its use in a prior art device would be *prima facie* obvious from the purpose disclosed in the reference. Furthermore, the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

In response to applicant's argument that the purposes of Natasi reference is to alter the mechanical strength of a prosthesis and not to alter the bioactivity of the surface of the coating, it is noted that the Natasi, as modified, satisfies all the structural limitations set forth in the apparatus claim. Moreover, the fact that Applicant uses the ions for a different purpose does not alter the conclusion that its use in a prior art device would be *prima facie* obvious from the purpose disclosed in the reference. Furthermore, the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessary make the claim patentable. *In re Best*,, 562 F.2d 1252, 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

In response to applicant's argument about ion implantation method in the apparatus claim and Natasi, it is noted that the method step recitation in claim 1, "the ions are incorporated into or onto the surface of the bone implant by ion beam implantation", it is noted that the method of forming the device is not germane to the issue of patentability of the device itself. Therefore, this limitation has not given patentable weight. Furthermore, the device of appear to be substantially identical to the device claimed, although produce by a different process, therefore the burden is upon the applicant to come forward with evidence establishing an unobvious difference between the two. *In re Marosi*, 218 USPQ 289 (Fed. Cir. 1983).

Applicant's arguments with regard to the different ranges, e.g. "up to a maximum depth of 200 nm" do not overcome the rejections applied thereto, since applicant has not provide any convincing **showing** that these are nothing more than optimum or workable values as asserted by the examiner. **Applicant has not provided any showing that such limitations are "critical".** *In re Cole*, 140 USPQ 230 (CCPA 1964); *In re Kuhle*, 188 USPQ 7 (CCPA 1975); *In re Davies*, 177 USPQ 381 (CCPA 1973). **Mere arguments by counsel cannot take the place of evidence.**

In re Cole, 236 F.2d 769, 773, 140 USPQ 230, 233 (CCPA 1964); In re Walters, 168 F.2d 79, 80, 77 USPQ 609, 610 (CCPA 1948); et al.

Furthermore, see previous response to arguments set forth in the office actions mailed on June 24, 2003 and January 27, 2004.

Allowable Subject Matter

Claim 14 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

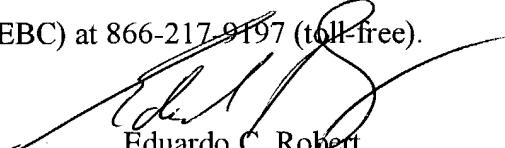
THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eduardo C. Robert whose telephone number is 703-305-7333. The examiner can normally be reached on Monday-Friday, 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P. Shaver can be reached on 703-308-2582. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Eduardo C. Robert
Primary Examiner
Art Unit 3732

E.C.R.